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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,781	12/03/2004	Silvio Aime	B-0459 US	5696
31834	7590	07/01/2008		
BRACCO RESEARCH USA INC. 305- COLLEGE ROAD EAST PRINCETON, NJ 08540			EXAMINER	
			JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER
			1618	
MAIL DATE	DELIVERY MODE			
07/01/2008	PAPER			

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/516,781	<b>Applicant(s)</b> AIME ET AL.
	<b>Examiner</b> D. L. Jones	<b>Art Unit</b> 1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1-9, 11-13 and 17-19 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) 1-9, 11-13, and 17-19 are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/06/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.      4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## PCT LACK OF UNITY

### Restriction into Groups

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, drawn to a MRI species of formula I.

Group II, claim(s) 1 and 9, drawn to a process of preparing MRI species.

Group III, claim(s) 11-13, drawn to intermediate compounds of formula II.

Group IV, claim(s) 1-5 and 17, drawn to a method of imaging organs/tissue.

Group V, claim(s) 1-5 and 18, drawn to a method of diagnosing tumors.

Group VI, claim(s) 19, drawn to a method of preparing an MRI species.

Note: Claims appearing in more than one group will be examined only to the extent that they read on the elected invention.

2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack a special technical feature that is distinguished over the prior art. In particular, McBride et al (US Patent No. 5,620,675) discloses a Formula II (see column 2, lines 5-39) that reads on the instant invention. In Formula II when X1 is a hydrophilic moiety the comprises an amino acid, polyamine species, or a monosaccharide; X2 is a polyamine species, an amino acid, or a monosaccharide; A1, A2, and C1 are independently L-amino acids; B1

is L-Phe; B2 is D- or L-Trp; B3 is D- or L-Lys; B4 is Thr, Phe, Leu, or Ile; and C2 is D- or L-Thr, Val, Phe, Leu, and Ile.

#### **ELECTION OF SPECIES**

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows those encompassed by Applicant's formula I as set forth in independent claim 1 and those of formula II as set forth in independent claim 11.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

**Note:** Applicant is respectfully requested to elect a single disclosed species from within the elected group. The species, if applicable to the elected group, should identify a specific D, a specific S, a specific N, the chelating ligand, and the precursor of D. In addition, Applicant is respectfully requested to identify the claims that read on the elected species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in that the species of formulae I and II may be used for imaging organs/tissues and diagnosing tumors. Independent claims 1 and 11 are generic to formulae I and II.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features as set forth above (see the explanation above about McBride et al, US Patent No. 5,620,675).

6. Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### **REJOINDER PARAGRAPH**

9. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/  
Primary Examiner  
Art Unit 1618

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